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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,668	09/30/2005	Kazuo Imose	TEI-0135	5514

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EXAMINER	
JANG, CHRISTIAN YONGKYUN	
ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
04/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,668	IMOSE, KAZUO	
	Examiner	Art Unit	
	CHRISTIAN Y. JANG	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/10/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 6th, 2009 has been entered.

Information Disclosure Statement

2. The information disclosure statement filed on September 10th, 2008 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. Note that only the document(s) crossed out have not been considered.

Specification

3. The amendments to the Specification have been accepted by the examiner.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-4 and 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turcott (USP #6,409,675) in view of Montserrat et al. ("Effectiveness of CPAP Treatment in Daytime Function in Sleep Apnea Syndrome"), and further in view of Krachman et al. ("Comparison of Oxygen Therapy with Nasal Continuous Positive Airway Pressure on Cheyne-Stokes Respiration During Sleep in Congestive Heart Failure")

6. As to claims 1 and 4, Turcott teaches an examination apparatus in use for patients with chronic heart failure (Abs), the apparatus comprising a biological information monitoring system (Fig. 1) with a unit for measuring and recording airflow information (410) and a unit for the analysis of the state of the sympathetic nerves based on the ECG wave (col. 15, lines 6-34), as well as an output part for displaying or printing both of a transition of respiratory airflow (410) and the enhanced state of sympathetic nerves (418). Although Turcott does not directly teach an electrode for measuring ECGs that are stuck on the skin of the subject in its preferred embodiment of an implantable device, it discloses the use of such a device (col. 3, lines 1-39), as well as another embodiment wherein the device is not implanted, in which the use of such a system would be obvious. Turcott does not disclose the use of the device in the selection of patients for whom an oxygen therapy is effective.

Montserrat teaches the use of an oxygen therapy (commonly known as a continuous positive air pressure therapy) and its effectiveness for the purpose of treating patients with SAHS (sleep apnea/hypopnea syndrome).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to recognize the use of the device as taught by Turcott in selecting patients for whom oxygen therapy is effective in order to improve the symptoms and perceived health status of those suffering from a sleep respiratory disturbance.

The combined teachings of Turcott and Montserrat fail to teach a use of an oxygen therapy using an oxygen-enriched gas for respiration of a patient. However, Krachman teaches that CPAP, which is taught by Montserrat, is equally as effective as oxygen therapy in use with patients with CHF.

As such, it would have been obvious to one having ordinary skill in the art at the time the invention was made to recognize the use of the device as taught by Turcott in selecting patients for whom oxygen therapy is effective as taught by Montserrat, and furthermore use oxygen-enriched gas therapy as opposed to CPAP as an obvious substitution in view of the teachings Krachman, which is known to be equally effective, and thus yielding predictable results.

7. As to claim 2, Turcott teaches the examination apparatus which comprises a unit for determining an electrocardiogram of the subject patient (col 7, lines 28-29), and an analysis unit for analyzing the enhanced state of sympathetic nerve based on the determined electrocardiogram wave form with a heart rate variability analytical procedure (col 7, lines 33-36).

8. As to claim 3, Turcott teaches the examination apparatus which comprises a sensor for detecting presence/absence or magnitude of respiratory airflow of the subject patient (Abstract), and an analysis unit (Fig. 1, 12) for analyzing synchronization of

transition of the respiratory state in a Cheyne-Stokes respiratory symptom in which apnea and respiratory states are repeated with transition of abnormal enhancement of sympathetic nerve (col 7, lines 42-47).

9. As to claims 6-9, Turcott, Montserrat, and Krachman teach a method of selecting a patient containing all the limitations found in the claims. The use of the system in claims 1-4 comprises the method claimed, and is rejected accordingly for the same reasoning.

10. As to claims 10-13, Turcott, Montserrat, and Krachman disclose the invention substantially as claimed. The combined teachings of Turcott, Montserrat, and Krachman do not teach selecting a patient who exhibits the results that an arterial oxygen saturation is not higher than a predetermined threshold value. However, Turcott's disclosure includes an optical sensor to determine arterial blood oxygen saturation. Oxygen toxicity, severe hyperoxia caused by breathing oxygen at elevated partial pressures, is a well known and established medical concept. Thus, it is the examiner's position that it would have been obvious for one of ordinary skill in the art to modify Turcott, Montserrat, and Thomas to exclude patients who exhibit oxygen levels above an established saturation point so that the therapy they receive do not result in hyperoxia.

11. Claims 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Turcott (USP #6,409,675), Montserrat et al., and Krachman et al., and further in view of Thomas et al. (US 2004/0144383).

12. As to claim 5, Turcott, Montserrat, and Krachman fail to teach the supplying apparatus allows the gas to be regulatable to a predetermined range. However, Thomas teaches the therapeutic system wherein the supplying apparatus of an oxygen-enriched gas for respiration is constituted to allow flow rate of the oxygen-enriched gas for respiration to be regulatable within a predetermined range so that the flow rate becomes the amount prescribed on the basis of the result displayed or printed by the output part of the examination apparatus ([0014], lines 1-11). As such, it would have been obvious to one of ordinary skill at the time of the invention to modify Turcott, Montserrat, and Krachman with the airflow regulation taught by Thomas so that the amount of oxygen delivered to the user is regulated to be in therapeutic range.

Response to Arguments

13. Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.

14. However, the examiner has chosen to address certain arguments by the applicant that are not persuasive.

15. Applicant has argued that the non-implantable monitor in Turcott has only the vascular plethsymography and arterial O_2 saturation sensor and cited the following in support (col. 11, lines 41-44):

> As with most of the sensors described here, the vascular plethysmography and arterial O_2 saturation sensors can be used in noninvasive, external embodiments, in contrast to incorporation in an implantantable monitor.

The Examiner respectfully disagrees with the applicant's interpretation of the statement. Turcott is not stating that it is *only* the two sensors that can be placed in an non-implantable device. Turcott is suggesting that these two sensors, along with most of the other sensors described, can be used in an external embodiment, while they cannot be used as an implantable monitor. Turcott further goes on to state that these optical sensors are particularly attractive for an external embodiment.

Furthermore, applicant has repeatedly reiterated that Turcott's invention is for an implanted monitor. However, as stated in the rejection, Turcott states that an external monitor can be used, along with most of the sensors taught by Turcott.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN Y. JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon. - Fri. (8AM-5PM) EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/C. Y. J./
Examiner, Art Unit 3735
4/13/09